Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Investigating the effect of oral acetazolamide compared to placebo on the severity of heart congestion in patients with heart failure

Protocol summary

Study aim
Determining the effect of oral acetazolamide tablets on the severity of congestive heart failure in patients with heart failure.

Design
This study is a single-center, double-blind randomized clinical trial with a ratio of 1:1 on the diuretic and anticongestive effects of oral acetazolamide in Iranian patients with heart failure (HF), which is conducted in phase three on 130 patients. Random number generator software will be used.

Settings and conduct
Place of study: Infusion Unit of Tehran Heart Center; Study population: patients with heart failure; Type of blinding: double blind; Blinding method: patients in the control group receive a placebo similar to acetazolamide . The outcome evaluator will not be aware of the type of intervention in the groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: obtaining 8 points from the EVEREST score; Age over 18 years; presence of a main clinical symptom of volume overload; maintenance treatment with oral furosemide; Use of SGLT2i drugs. Non-inclusion criteria: systolic blood pressure less than 90 mmHg or mean arterial pressure less than 65 mmHg; estimated glomerular filtration rate less than 20 ml/min/1.73 m2; use of any diuretic agent except mineralocorticoid receptor antagonists; Simultaneous diagnosis of acute coronary syndrome

Intervention groups
The intervention group will receive acetazolamide tab 500 mg on day zero, then 250 mg bd for two days and 250 mg on the third day The control group will receive placebo equivalent to acetazolamide.

Main outcome variables
Sodium to creatinine ratio on the third day of the study; NT-proBNP level on the 30th day of the study; quality of life questionnaire score three months later

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230527058306N1**
Registration date: **2023-07-08, 1402/04/17**
Registration timing: **prospective**

Last update: **2023-07-08, 1402/04/17**
Update count: **0**

Registration date
2023-07-08, 1402/04/17

Registrant information

Name
Houshang Bavandpour karvane

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 83 3467 6290

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-23, 1402/05/01

Expected recruitment end date
2025-07-23, 1404/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating the effect of oral acetazolamide compared to placebo on the severity of heart congestion in patients with heart failure

Public title
Efficacy of Oral Acetazolamide on Decongestion in Patients With Heart Failure

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Earn at least 8 points from EVEREST score Patients over 18 years old The main clinical sign of volume overload includes edema, ascites confirmed by abdominal ultrasound Pleural effusion confirmed by chest X-ray or chest ultrasound without intravenous furosemide Maintenance treatment with oral furosemide as a loop diuretic ≥20 mg for at least one month Using SGLT2i drugs including canagliflozin, dapagliflozin, and empagliflozin for at least one month

Exclusion criteria:
Systolic blood pressure less than 90 mmHg or mean arterial pressure less than 65 mmHg Estimated glomerular filtration rate (eGFR) <20 ml/min/1.73 m2 Using any diuretic agent except mineralocorticoid receptor antagonists including spironolactone and eplerenone Simultaneous diagnosis of acute coronary syndrome, which is characterized by typical chest pain in addition to an increase in troponin level above the 99th percentile or electrocardiographic changes indicating ischemia or hospitalization as unstable angina.

Age
From **18 years** old to **90 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **130**

Randomization (investigator's opinion)
Randomized

Randomization description
A simple randomization method is used, in which the randomization unit is individual, and random sequence generation software (Random Number Generator software) is used. For concealment, non-transparent sealed envelopes with a random sequence is used . In this method, each random number created is recorded on a card and the cards are placed inside the envelopes in order.In order to maintain the random sequence of the envelopes on the outer surface, the numbering is done in the same order. Finally, the lids of the envelopes are glued and placed in a box. At the time of registration of the participants, based on the order of entry of the eligible participants into the study, one of the envelopes will be opened and the allocated group of that participant will be revealed.

Blinding (investigator's opinion)
Double blinded

Blinding description
To blind the participants, in the control group, instead of acetazolamide, a placebo with the same shape, color, smell and taste as acetazolamide will be given. On the other hand, the outcome evaluator will not know which group received which drug.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Tehran Heart Center; Tehran University of Medical Sciences

Street address
Tehran Heart Center; corner of Jalal El Ahmad Highway; North Kargar St.

City
Tehran

Province
Tehran

Postal code
13138-14117

Approval date
2023-05-27, 1402/03/06

Ethics committee reference number
IR.TUMS.THC.REC.1402.016

Health conditions studied

1

Description of health condition studied
Chronic congestive heart failure

ICD-10 code
I50.42

ICD-10 code description
Chronic combined systolic (congestive) and diastolic (congestive) heart failure

Primary outcomes

1

Description
Random urine sodium to creatinine ratio

Timepoint
The third day of study

Method of measurement
Urine and blood tests

Secondary outcomes

1

Description
B-type natriuretic peptide
Timepoint
Thirty days of study
Method of measurement
Blood test

Intervention groups

1

Description
Intervention group: They will receive acetazolamide 500 mg tablets in addition to intravenous furosemide on day 0, then 250 mg in addition to oral furosemide on day 2 for two days, and 250 mg acetazolamide plus single dose furosemide on day 3.
Category
Treatment - Drugs

2

Description
Control group: They will receive placebo in addition to intravenous furosemide on day 0, then placebo plus oral furosemide on day 2 for two days, and placebo plus single dose furosemide on day 3.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Heart center
Full name of responsible person
Houshang Bavandpour Karvane
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Houshang Bavandpour karvane
Position
Resident of cardiology
Latest degree
Medical doctor
Other areas of specialty/work
Cardiology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
All data is potentially shareable after de-identifying individuals
When the data will become available and for how long
Access begins six months after the announcement of the results
To whom data/document is available
All people will have access
Under which criteria data/document could be used
There is no special condition
From where data/document is obtainable
Tehran Heart center
What processes are involved for a request to access data/document
Applications are accepted within a month and information is available to the applicant
Comments